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PATENT  
Attorney Docket No. 5474 US

Claim Listing:

1. (withdrawn) A method of treating, preventing or managing lupus which comprises administering to a patient in need of such treatment a therapeutically or prophylactively effective amount of clofarabine or a pharmaceutically acceptable salt, stereoisomer, solvate, hydrate, clathrate, prodrug or metabolite thereof.
2. (withdrawn) The method of claim 1 wherein the lupus is cutaneous lupus erythematosus, chronic cutaneous lupus erythematosus, subacute cutaneous lupus erythematosus, acute lupus erythematosus, systemic lupus erythematosus, drug-induced lupus, neonatal lupus, discoid lupus, or lupus-in-overlap.
3. (withdrawn) The method of claim 1 wherein the patient is a mammal.
4. (withdrawn) The method of claim 3 whercin the mammal is a human.
5. (withdrawn) The method of claim 4 wherein the human is an adult.
6. (withdrawn) The method of claim 4 wherein the human is an adolescent.
7. (withdrawn) The method of claim 4 wherein the human is a child.
8. (withdrawn) The method of claim 4 wherein the human is an infant.
9. (withdrawn) The method of claim 1 further comprising the administration of an additional therapeutic agent.
10. (withdrawn) The method of claim 10 wherein the additional therapeutic agent is an antibiotic, an antiemetic agent, an antidepressant, and antifungal agent, an antiinflammatory agent,

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an antiviral agent, an immunomodulatory agent, an antimalarial agent, a beta-interferon, an alkylating agent, a hormone or a cytokine.

11. (withdrawn) The method of claim 1 wherein the therapeutically or prophylactively effective amount is greater than 0.01 mg/kg/day.

12. (withdrawn) The method of claim 1 wherein the therapeutically or prophylactively effective amount of clofarabine is from about 5 mg/kg/day to about 75 mg/kg/day.

13. (withdrawn) The method of claim 12 wherein the therapeutically or prophylactively effective amount of clofarabine is from about 20 mg/kg/day to about 60 mg/kg/day.

14. (withdrawn) The method of claim 13 wherein the therapeutically or prophylactively effective amount of clofarabine is from about 40 mg/kg/day to about 50 mg/kg/day.

15. (withdrawn) The method of claim 1 wherein the therapeutically or prophylactively effective amount of clofarabine is administered parenterally.

16. (withdrawn) The method of claim 1 wherein the therapeutically or prophylactively effective amount of clofarabine is administered orally.

17. (Currently Amended) A pharmaceutical composition for the treatment of lupus which comprises ~~about 0.1 mg to about 1000 mg of~~ clofarabine, or a pharmaceutically acceptable salt, hydrate, clathrate, solvate, prodrug, metabolite or stereoisomer thereof in a therapeutically effective amount for the treatment of lupus and a pharmaceutically acceptable carrier.

18. (Currently Amended) A pharmaceutical composition for the treatment of lupus which comprises a therapeutically effective amount of clofarabine, which wherein the effective amount is

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sufficient to treat lupus for which is insufficient and insufficient to cause adverse affects associated with purine nucleosides.

19. (Currently Amended) A pharmaceutical composition for the treatment of lupus which comprises a therapeutically effective amount of clofarabine, wherein the effective amount is sufficient to treat lupus and insufficient to cause adverse affects associated with purine nucleosides, and a therapeutically effective amount of at least one other immunomodulatory agent which is sufficient to treat lupus for which is insufficient to cause adverse affects associated with purine nucleosides and a pharmaceutically acceptable carrier.

20. (New) The pharmaceutical composition of claim 17, wherein the therapeutically effective amount of clofarabine is in a range from about 1.25 mg/kg/day to about 10 mg/kg/day.

21. (New) The pharmaceutical composition of claim 17, wherein the therapeutically effective amount of clofarabine is in a range from about 2 mg/kg/day to about 6 mg/kg/day.

22. (New) The pharmaceutical composition of claim 17, wherein the therapeutically effective amount of clofarabine is in a range from about 4 mg/kg/day to about 5 mg/kg/day.

23. (New) The pharmaceutical composition of claim 19, wherein the immunomodulatory agent is selected from the group consisting of methotrexate, leflunomide, cyclophosphamide, cytoxan, Immuran, cyclosporine A, minocycline, azathioprine, antibiotics, tacrolimus, methylprednisolone, corticosteroids, steroids, mycophenolate mofetil, rapamycin, sirolimus, mizoribine, deoxyspergualin, brequinar, malononitriloamides, T cell receptor modulators, and cytokine receptor modulators.

24. (New) The pharmaceutical composition of claim 19, wherein the immunomodulatory agent is methotrexate.

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25. (New) The pharmaceutical composition of claim 19, wherein the immunomodulatory agent is leflunomide.
26. (New) The pharmaceutical composition of claim 19, wherein the immunomodulatory agent is cyclophosphamide.
27. (New) The pharmaceutical composition of claim 19, wherein the immunomodulatory agent is cyclosporine A.
28. (New) The pharmaceutical composition of claim 19, wherein the immunomodulatory agent is tacrolimus.
29. (New) The pharmaceutical composition of claim 19, wherein the immunomodulatory agent is mycophenolate mofetil.
30. (New) The pharmaceutical composition of claim 19, wherein the immunomodulatory agent is rapamycin.
31. (New) The pharmaceutical composition of claim 19, wherein the immunomodulatory agent is sirolimus.
32. (New) The pharmaceutical composition of claim 17 in a dosage form suitable for oral, mucosal, parenteral, transdermal, or topical administration.
33. (New) The pharmaceutical composition of claim 17 in a dosage form suitable for oral administration.
34. (New) The pharmaceutical composition of claim 17 in a dosage form suitable for parenteral administration.

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35. (New) The pharmaceutical composition of claim 19 in a dosage form suitable for oral, mucosal, parenteral, transdermal, or topical administration.

36. (New) The pharmaceutical composition of claim 19 in a dosage form suitable for oral administration.

37. (New) The pharmaceutical composition of claim 19 in a dosage form suitable for parenteral administration.

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